510(k) SUMMARY

MAY 3 1 2013

ImpediMed Limited's L-Dex® U400

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date of summary prepared: February 8, 2013

Proprietary Device Name / Common Name / Classification

Trade/Proprietary name:	L-Dex® U400 BIS Extra Cellular Fluid Analysis
Classification name:	Impedance Plethysmograph
Regulation number/CFR section:	21 C.F.R. § 870.2770
Product code:	OBH
Regulation Medical Specialty:	Cardiovascular
Review Panel:	Gastroenterology/Urology
Device class:	Class II

Predicate Devices

ImpediMed Limited, L-Dex® U400 BIS Extra Cellular Fluid Analysis (K100811)

Intended Use / Indications for Use

The L-Dex® U400 is a bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men.

The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated.

Lymphedema Analysis PC Software - an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 device for uploading data on to the PC from the L-Dex U400, processing and analyzing of bioimpedance measurements.

Technological Characteristics / Principles of Operation

The ImpediMed L-Dex® U400 Extra Cellular Fluid Analysis device is a battery powered bioimpedance spectroscopy device operating in tetra-polar mode via a set of leads that are attached to self-adhesive skin electrodes by means of alligator clips. The subject device accurately measures current, voltage and phase angle, and calculates three bioimpedance parameters: impedance (Z), resistance (R) and reactance (Xc). These measurements and calculations are used to estimate extracellular fluid ratios, and calculate the Lymphedema Index or L-Dex

The L-Dex U400 measures bioimpedance parameters over a frequency range of 4 - 1000 kHz with 256 data points. An on-screen graph displays the raw measured data in the form of a resistance vs. reactance complex impedance plot. These bioelectrical parameters are then used in algorithms to give an L-Dex value for the affected compared to the unaffected limb.

Measured impedance ratios (L-Dex values) and normal ranges are shown on the device immediately after measurement and stored for later reference. Measured data may be transferred to the ImpediMed Impsoft database software. The Impsoft software adds extra functionality and ease of data management, including viewing patient histories and printing reports.

Performance Data

The company has provided an overview of reports in the literature that describes the use of the device for its indications for use.

Substantial Equivalence

The L-Dex® U400 is as safe and effective as the company's cleared device of the same name (K100811). The L-Dex® U400 has the same intended use, technological characteristics, and principles of operation and similar indications as its predicate device. The minor change in indications for use between the subject and cleared device does not impact the diagnostic effect of the L-Dex® U400. Performance data demonstrate that the subject device is as safe and effective as the company's predicate device for the proposed indications for use. Thus, the L-Dex® U400 is substantially equivalent.

Substantial Equivalence Table			
	Subject Device	Predicate Devices	
	L-Dex® U400	L-Dex® U400	L-Dex® U400
K Number		K100811	K080825
Class	Class II	Class II	Class II
Regulation	870.2770	870.2770	870.2770
Common Name	L-Dex	L-Dex	L-Dex
Intended Use	A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men. The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated. Lymphedema Analysis PC Software - an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 device for uploading data on to the PC from the L-Dex U400, processing and analyzing of bioimpedance measurements.	A bioelectrical impedance analyser/monitor for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men. The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated. This device is not intended to diagnose or predict lymphedema of and extremity. Lymphedema Analysis PC Software - an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 device for uploading data on to the PC from the L-	A bioelectrical impedance analyser/monitor utilizing impedance ratios that supports the measurement of extracellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphedema of the arm women. This device is not intended to diagnose or predict lymphedema of and extremity. Lymphedema Analysis PC Software - an optional PC software package that is intended to be used only with the ImpediMed L-Dex U400 device for uploading data on to the PC from the L-Dex U400, processing and analyzing of bioimpedance measurements.

		Dex U400, processing and analyzing of bioimpedance measurements.	
Principle	Bioelectrical impedance in the range of 4 kHz to 1000 kHz (256 frequencies)	Bioelectrical impedance in the range of 4 kHz to 1000 kHz (256 frequencies)	Bioelectrical impedance in the range of 4 kHz to 1000 kHz (256 frequencies)
Dimensions	L=190mm, W=130mm, D=110mm	L=190mm, W=130mm, D=110mm	L=190mm, W=130mm, D=110mm
Weight	I kg / 2.2 lbs(including battery)	I kg / 2.2 lbs(including battery)	I kg / 2.2 lbs(including battery)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

ImpediMed Limited
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street, NW
WASHINGTON DC 20004

Re: K130338
Trade/Device Name: L-Dex® U400
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: OBH
Dated: May 7, 2013
Received: May 7, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130338

Device Name: L-Dex® U400

Indications for Use:

A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in women and the leg in men.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130338